UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-CV-12257-PBS
THIS DOCUMENT RELATES TO: *State of Iowa v. Abbott Laboratories, et al.*	Judge Patti B. Saris

MEMORANDUM IN SUPPORT OF TEVA PHARMACEUTICALS USA, INC. AND NOVOPHARM USA, INC.'S MOTION TO COMPEL

Defendants Teva Pharmaceuticals USA, Inc. and Novopharm USA, Inc. (collectively, "Teva") bring this motion to compel Plaintiff, the State of Iowa ("State"), to produce documents and information responsive to its discovery requests, including: (1) documents relating to the State's knowledge of and/or calculation of the Average Manufacturer Prices ("AMPs") for Teva's drugs, (2) the identity of current or former State employees allegedly misled by Teva with regard to the prices of Teva's drugs, and (3) the steps taken by the State to ensure that it paid Iowa Medicaid providers no more than the actual acquisition costs of Teva's drugs.

INTRODUCTION

The State refuses to produce documents and information that are plainly discoverable and relevant to the claims and defenses in this litigation. The State alleges in its Complaint that Defendants, including Teva, deceived and defrauded the Iowa Medicaid program by reporting to drug pricing compendia Average Wholesale Prices ("AWPs") that did not approximate Medicaid providers' actual drug acquisition costs.[1] The documents and information requested by Teva

[1] *See* Compl. at ¶¶ 652-662.

relate directly to a central issue in this case: whether the State knew that Teva's AWPs did not approximate providers' acquisition costs. Teva's requests are therefore directly relevant to the claims and defenses in this litigation, and the State's refusal to produce responsive documents and information has no merit. Accordingly, Teva respectfully moves to compel Plaintiff to produce documents responsive to Document Request Number 7 and provide complete responses to Interrogatory Numbers 3 and 5.

BACKGROUND

On February 27, 2009, Teva served the State with its First Set of Requests for Production and First Set of Interrogatories.[2] Among other documents and information, Teva's discovery requests seek:

- "All Documents constituting, concerning or relating to Your deliberation and/or decision to request or not to request AMP data from Teva for its Subject Drugs, including all documents containing any AMP data for any Subject Drug and all documents concerning the calculation of an AMP from a URA" (Document Request Number 7);

- Identification of "each person currently or formerly employed by the State of Iowa You allege was misled by Teva with respect to the actual prices of the Teva Subject Drugs and the manner in which they were misled" (Interrogatory Number 3); and

- Identification of "each and every step taken by You prior to and after the filing of the Complaint to ensure that You paid providers no more than their actual acquisition costs for the Teva Subject Drugs" (Interrogatory Number 5).

The State served its responses to Teva's requests for production on March 30, 2009, and served its responses to Teva's interrogatories on April 29, 2009.[3] In response to each of the requests

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[2] *See* Defendant Teva Pharmaceuticals USA, Inc.'s First Set of Requests for Production to Plaintiff, the State of Iowa (attached as Exhibit 1); Defendants Teva Pharmaceuticals USA, Inc. and Novopharm USA, Inc.'s First Set of Interrogatories to Plaintiff, the State of Iowa (attached as Exhibit 2).

[3] *See* State of Iowa's Objections and Responses to Teva Pharmaceuticals USA, Inc.'s First Set of Requests for Production to Plaintiff, the State of Iowa (attached as Exhibit 3); State of Iowa's Objections and Responses to (Continued…)

highlighted above, the State objected on various grounds and refused to provide the requested discovery. While the State's objection to Interrogatory Number 3 challenged the relevance of the requested discovery, the reasons for the State's refusal to provide discovery responsive to Request for Production Number 7 and Interrogatory Number 5 are less clear. Among other things, the State objected that these requests seek the production of privileged material and material from outside the relevant time period. But these objections do not explain the State's outright refusal to respond to these requests.

On September 23, 2009, counsel for the parties met and conferred regarding the State's responses to Teva's discovery requests. Counsel for the State indicated that the State would take Request for Production Number 7 "under advisement," but repeated the State's refusal to respond to Interrogatory Numbers 3 and 5.[4] On October 16, 2009, the State served supplemental written responses to Teva's discovery requests, but again refused to provide documents or information responsive to Request for Production Number 7, or Interrogatory Numbers 3 and 5.[5]

ARGUMENT

Under the Federal Rules of Civil Procedure, "[p]arties may obtain discovery regarding *any nonprivileged matter* that is relevant to any party's claim or defense. . . ." Fed. R. Civ. P. 26(b)(1) (emphasis added). The definition of "relevant information" in Rule 26(b)(1) is extremely broad. "Relevant information need not be admissible at the trial if the discovery appears *reasonably calculated* to lead to the discovery of admissible evidence." *Id*. (emphasis

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Defendants Teva Pharmaceuticals USA, Inc. and Novopharm USA, Inc.'s First Set of Interrogatories to Plaintiff, the State of Iowa (attached as Exhibit 4).

4 *See* Sept. 25, 2009 Letter from J. Parish to J. Normand (attached as Exhibit 5).

5 *See* State of Iowa's Supplemental Responses to Defendants Teva Pharmaceuticals USA, Inc. and Novopharm USA, Inc.'s First Set of Requests for Production and Interrogatories (attached as Exhibit 6).

added). It is well-established that information is discoverable if there is *any possibility* that it is relevant to some claim or defense in the litigation. *See, e.g., Oppenheimer Fund, Inc. v. Sanders,* 437 U.S. 340, 351 (1978) (relevance is broadly construed "to encompass any matter that bears on, or that reasonably could lead to other matter that could bear on, any issue that is or may be in the case."). Here, the State has refused to produce documents and information that are directly relevant to the claims and defenses in this litigation.

I. DOCUMENTS REGARDING THE STATE'S KNOWLEDGE OF AND/OR CALCULATION OF AMPs ARE RELEVANT AND SHOULD BE PRODUCED.

Teva seeks documents regarding the State's "deliberation and/or decision to request or not to request AMP data from Teva for its Subject Drugs, including all documents containing any AMP data for any Subject Drug and all documents concerning the calculation of an AMP from a URA."[6] This request includes: (1) documents containing AMP data for the Teva Subject Drugs, (2) documents concerning the State's deliberation and/or decision to request or not request AMP data for the Teva Subject Drugs, and (3) documents concerning the "reverse engineering" or calculation of AMPs.[7] While the State objects that this Request calls for the production of privileged documents and documents from outside the relevant time period, its objections do not explain its outright refusal to respond to this Request.[8]

"AMP" is the average price paid to manufacturers by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting common discounts and price reductions. *See*

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6 Ex. 1 at 14.

7 Ex. 5 at 2.

8 Notably, in its supplemental responses to Defendants' joint discovery requests, the State concedes the relevance of these documents by agreeing to produce "documents relating to AMPs and FULs from 1992-2005 to the extent they exist and have not already been produced." State of Iowa's Supplemental Responses to Defendants' First Set of Requests for Production and Interrogatories at 2-3 (attached as Exhibit 7).

42 U.S.C. § 1396r-8(k)(1). Because AMPs for generic drugs by regulation must generally include the discounts and other price reductions available to providers and other purchasers, they are, at the very least, a reasonable conservative approximation of acquisition cost in generic markets. The requested documents are relevant because, to the extent the State knew the AMPs for Teva's products, it could not have been deceived, defrauded, or in anyway misled regarding the relationship between AWP and pharmacy acquisition cost. To prevail on its common law fraud claim, the State must prove that it justifiably relied on Teva's AWPs to estimate drug acquisition costs. *See In re Marriage of Spiegel*, 553 N.W.2d 309, 317 (Iowa 1996). But the State cannot meet this burden if the evidence shows that it knew the AMPs for Teva's drugs, as such evidence negates the reasonableness of the State's choice to rely on AWP as a basis for estimating acquisition cost. Likewise, if the State knew the AMPs for Teva's drugs, it cannot establish that Teva engaged in a deceptive or unfair practice within the meaning of the Consumer Fraud Act. Because the requested documents would undercut key elements of the State's claims, they are relevant and should be produced.

II. INFORMATION REGARDING THE IDENTITY OF CURRENT OR FORMER STATE EMPLOYEES ALLEGEDLY MISLED BY TEVA IS RELEVANT AND SHOULD BE PRODUCED.

Teva requests that the State identify "each person currently or formerly employed by the State of Iowa You allege was misled by Teva with respect to the actual prices of the Teva Subject Drugs and the manner in which they were misled."[9] The State objected to this Interrogatory as "burdensome and harassing" and objected that the requested information was not relevant. But this information is directly relevant to key elements of the State's claims.

[9] Ex. 2 at 10.

To prove common law fraud, the State must—in addition to proving justifiable reliance—prove that the alleged fraud was the proximate cause of its damages. *Robinson v. Perpetual Servs. Corp.*, 412 N.W.2d 562, 567-68 (Iowa 1987) (the defendant's actions "must be a substantial factor in bringing about plaintiff's harm."). If no State employee was misled as to the actual prices of Teva's drugs, then the State's reliance on AWP was not justifiable and was not the cause of the State's alleged injury. Similarly, as a part of its Consumer Fraud Act claim, the State has claimed that Teva's "deceptive and unfair practices" "caused great harm to Iowa."[10] If no State employee was misled or deceived as to the actual prices of Teva's drugs, then any alleged injury to Iowa was not caused by Teva. Accordingly, the requested information is both discoverable and relevant and should be produced.

III. INFORMATION REGARDING THE STEPS ALLEGEDLY TAKEN BY THE STATE TO ENSURE IT PAID PROVIDERS NO MORE THAN THE ACTUAL ACQUISITION COST IS RELEVANT AND SHOULD BE PRODUCED.

In its Complaint, the State alleges that, consistent with federal regulations, it made "good faith efforts to reimburse providers at [estimated acquisition cost]."[11] Thus, Teva requests that the State identify "each and every step taken by You prior to and after filing of the Complaint to ensure that You paid providers no more than their actual acquisition costs for the Teva Subject Drugs."[12] But the State has refused to provide this information.

Teva is entitled to know what the State's "good faith efforts" were, as they bear directly on the reasonableness of the State's choice to rely on AWP as a basis for estimating acquisition

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10 Compl. at ¶655.

11 *Id.* at ¶ 85.

12 Ex. 2 at 11.

cost. This information is also relevant to a number of affirmative defenses, including the State's failure—even now—to mitigate its damages.[13] Accordingly, it should be produced.

CONCLUSION

For all of the foregoing reasons, Teva respectfully requests that the Court order the State of Iowa to produce documents and information responsive to Request for Production Number 7 and Interrogatory Numbers 3 and 5.

Dated: January 7, 2010

Respectfully submitted,

/s/ Jennifer G. Levy

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[13] Answer and Affirmative Defenses of Teva Pharmaceuticals USA, Inc., Novopharm USA, Inc. and Sicor Inc. to the State of Iowa's Complaint at 35 ("Plaintiff's claims are barred, in whole or in part, (1) because Plaintiff failed to mitigate damages. . . .").

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of January, 2010, a true and correct copy of the foregoing Memorandum in Support of Teva Pharmaceuticals USA, Inc. and Novopharm USA, Inc.'s Motion to Compel was electronically served on all counsel of record by transmission to LexisNexis File & Serve.

/s/ Jennifer G. Levy
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